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(71) Applicant *(for all designated States except US)*: **UNOMEDICAL A/S** [DK/DK]; Birkerød Kongevej 2, DK-3460 Birkcrød (DK).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **GYRN, Steffen** [DK/DK]; Brogade 12, 3., DK-4100 Ringsted (DK). **HØRDUM, Elo, Lau** [DK/DK]; Stenhavevej 14E, DK-2970 Hørsholm (DK).

(74) Agent: **NILAUSEN, Kim**; ZACCO DENMARK A/S, Hans Bekkevolds Allé 7, DK-2900 Hellerup (DK).

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(54) **Title**: SEALING BETWEEN A CANNULA PART AND A FLUID PATH

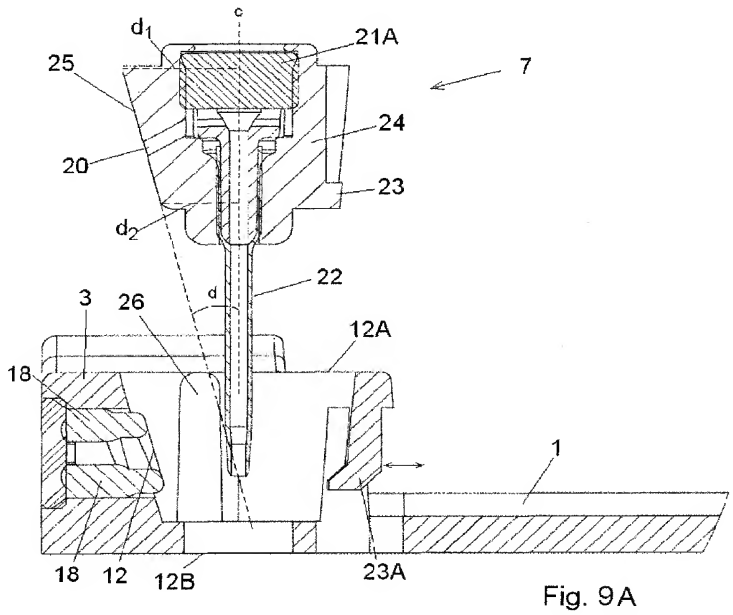

Fig. 9A

(57) **Abstract**: The application relates to an infusion part comprising a cannula part (7) and a fluid path, whereby a sealing (18) is positioned between the cannula part and the inlet/outlet opening (12) of the fluid path when the cannula part is in position for use in order to keep the fluid path to the cannula tight. The sealing (18) is surrounding the inlet/outlet opening (12) and/or the distance di between a centre line c of the cannula part and a point on the outer surface of the cannula part positioned at or above the upper edge of the sealing (18) is larger than the distance 02 between the centre line c of the cannula part and a point on the outer surface of the cannula part positioned at or below the lower edge of the sealing.

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Sealing between a cannula part and a fluid path

The technical field

The invention relates to an infusion part comprising a cannula part and a fluid path for providing continuous administration of a therapeutically working substance, such as insulin. The infusion part can be connected to delivery means which means provide e.g. controlled dosage of medication or nutrients.

Prior art

WO 2007/071258 describes a medical device for delivering fluid comprising an injection part and a fluid delivery part where the fluid delivery part and the injection part can be separated and rejoined. The fluid delivery part comprises a reservoir, means for transport of liquid e.g. in form of a pump and a house in which the active units of the delivery part is placed. The injection part comprises: a base plate, a cannula part comprising a body with a through going opening provided with a cannula extending past the proximal side of the base plate and means for fixation of the base plate to the skin of the user e.g. in the form of a mounting pad. The cannula part is provided with one or more openings leading fluid to a hollow in the cannula part and each opening is covered with a self closing membrane. The delivery part and the injection part is assembled through a connector comprising a fluid path leading fluid from the reservoir to the through-going opening in the cannula part which fluid path comprises means for blocking access to the injection part when the connector is disconnected from the delivery part and/or the injection part. The embodiments illustrated in this document are quite complex and not easy to manufacture.

EP 652 027 discloses an infusion device to be placed on a patients skin for delivering of medication. This infusion device comprises a cannula device (10) carrying a penetrating cannula of steel. The cannula device (10) is concentric i.e. all parts of the cannula device are rotational symmetric with respect to rotation around the common axis. The cannula device (10) can slide axially and has a channel (11) with an inlet opening in the cylindrical side surface which inlet opening corresponds to an outlet opening of a channel (7) through which medication or the like is entering. Above and below the outlet of the channel (7) is placed a first and a second O-ring (8). Both O-rings (8) are placed in circular grooves in the inner surface of the surrounding the house (1). In this device the inserter and the cannula device are permanently joined

together and this allows the cannula device to be at least partly inserted into a cannula opening which fits tightly around the cannula device even before insertion of the cannula device has taken place i.e. this results in that there are friction between the cannula part and the inner surface of the house during the entire insertion procedure. Also there is no teaching in this document of how to adapt the use of a soft cannula to this device.

The invention

The object of the invention is to provide an infusion part allowing the use of a soft cannula which is safe and simple to manufacture and which reduces the friction between the cannula part and the base part and therefore also the risk of incorrect positioning of the cannula part during insertion. This object is achieved by reducing the time where both the moving cannula part and the inner surface of the opening for receiving the cannula part are in contact with the gasket sealing of fluid from the surroundings. This can generally be achieved by creating a cannula part having an increasing diameter or by creating a sealing with a smaller area.

This object is achieved by an infusion part as described in claim 1 comprising a cannula part and a fluid path, where

- the cannula part comprises a body formed by a hard material which body has an inner through going opening which through going opening is in fluid contact with a cannula, the cannula has an inner opening which provides fluid contact with the patient, the body of the cannula part has an opening corresponding to the inlet or outlet opening of the fluid path resulting in fluid contact between the fluid path and the cannula part and these two corresponding openings do, when they are positioned opposite each other, allow unrestricted flow,
- the fluid path comprises at least one inlet and one outlet opening through which a fluid can enter and exit the fluid path, and
- a sealing is positioned between the cannula part and the inlet/outlet opening of the fluid path when the cannula part is in position for use in order to keep the fluid path to the cannula tight.

The sealing is surrounding the inlet/outlet opening *and/or* the distance d_1 between a centre line c of the cannula part and a point on the outer surface of the cannula part positioned at or above the upper edge of the sealing is larger than the distance d_2 between the centre line c of the cannula part and a point on the outer surface of the cannula part positioned at or below the lower edge of the sealing. "Upper edge of the sealing" defines the part of the sealing or gasket which has the longest distance to the patient's skin, and "lower edge of the sealing" defines the part of the sealing which has the shortest distance to the patient's skin when the infusion part according to the invention is inserted in a use position.

According to one embodiment the body of the cannula part is provided with a sealing before use or alternatively the opening of the fluid path or the surface surrounding the opening of the fluid path is provided with a sealing before use. "Provided" means that the sealing or gasket is somehow attached to the indicated surface, it might just be placed in a groove or a cavity as indicated in fig. 9 or 10.

According to one embodiment the penetrating member is provided with attachment means assuring that the penetrating member is unreleasably attached to the base part after insertion.

According to one embodiment the body of the cannula part is provided with a sealing or gasket placed along the edge of the opening through which fluid enters or exits the cannula part.

According to one embodiment the opening of the fluid path corresponding to an opening of the cannula part is provided with a sealing placed along the edge of the opening i.e. in a short distance from the opening. "A short distance" is understood to be less than or equal to the distance equaling the diameter of the opening and if the opening is not round: less than or equal to the longest dimension of the opening.

The sealing material according to any embodiment can be hydrophobic and elastic e.g. the sealing material is made of silicone.

According to an embodiment the body of the cannula part has at least one second opening to the inner through going opening and preferably this at least one second opening to the inner through going opening is covered by a self closing membrane which membrane can be penetrated by a blunt or pointy needle and can be made of silicone.

This at least second opening can e.g. be used for insertion of the device if the cannula is a soft cannula not able to cut its way through the patients skin, then a separate insertion needle can pass through the second opening, all through the cannula and provide a cutting edge in front of the cannula. It can also be used for supplying medication or nutrients which only are given to the patient in smaller doses a few times a day.

According to an embodiment the infusion part comprises a base part which can be fastened to a patient's skin.

According to one embodiment of such an infusion part the base part is provided with an opening corresponding to the profile at the non-penetrating end of the cannula part.

The "non-penetrating end" of the cannula part is the end opposite the cannula i.e. the distal end of the penetrating member where "distal" indicates the end is turned away from the patient. In the embodiment of the cannula part shown in the figs. 4A, 4B and 4C the cannula part has a flat surface part on one side corresponding to a flat wall surrounding the opening of the fluid path, i.e. that the opening is "adapted" means that the surrounding walls correspond to the cannula part and assures that the cannula part ends up in a well-defined and

close fitted – preferably press-fitted - position. "Press-fitted" means that it is so close fitted that it requires a force to insert the cannula part.

According to this embodiment the opening can extend below the outer surface of the base part providing walls which tightly fits around the cannula part when the cannula part is inserted into the patient and preferably the inlet or outlet opening of the fluid path opens into the wall of the opening fitting around the cannula part and when the cannula part is inserted, an inlet or outlet to the inner opening of the cannula part corresponds to the inlet/outlet opening of the fluid path.

According to one embodiment the distance d_1 between a centre line c of the cannula part and a point on the outer surface of the cannula part positioned at the upper edge of the sealing (18) is larger than the distance d_2 between the centre line c of the cannula part and a point on the outer surface of the cannula part positioned at the lower edge of the sealing. The centre line c is parallel to the direction of insertion.

According to one embodiment the angle d is the angle between the direction of insertion of the cannula part and a plane being tangent to the surface surrounding the opening opposite the sealing, and $0 < d \leq 90^\circ$, normally $45 \leq d \leq 80^\circ$ and most often $70 \leq d \leq 80^\circ$.

When a cannula part with a decreasing cross-section is inserted into a hollow with a corresponding decreasing hollow then the cannula part can be press-fitted into the hollow. This press-fitting both assures that the two corresponding openings of respectively the fluid path and the cannula part are pressed together thereby improving the fluid tight connection between them and it can also lock the cannula part to the base part.

According to one embodiment the base part is formed at least partly of a hard material. That a material is "hard" means that it can not be penetrated by a

needle, and also that it is able to maintain a shape it is given during production although it might be possible to flex the material due to the shape it is given e.g. if it is formed as a thin plate or if it is very long but it will not be possible to compress it i.e. reduce it size.

According to one embodiment the fluid path is formed as an integrated part of the base part fastened to the patient's skin. That the fluid path is formed as an integrated part means that it is an unreleasable part of the device, i.e. it is permanently attached to the device at some time during the manufacturing process of the base part and when the base part is in use it will not be possible to separate the fluid path and the rest of the base part.

According to one embodiment the hard material is a molded plastic material e.g. the plastic material is polypropylene.

According to one embodiment the base part comprises fastening means for attaching delivery means to the base part. The delivery means can comprise a connecting part provided with means corresponding to the means for fastening of delivery means and provided with a tube for transferring medication to the infusion part or the delivery means can comprise a reservoir containing medication and means for transferring medication to the infusion part. The means for transferring will normally be a pump and a programmable part possibly combined with a sensor for assuring appropriate amounts of medication to be delivered to the patient.

Embodiments of the invention will now be described with reference to the figures in which:

Figure 1 shows a first embodiment of an infusion part according to the invention.

Figures 2 and 2A shows a second embodiment of an infusion part according to the invention.

Figure 3 shows the same embodiment of an infusion part as figs. 2 and 2A.

Figure 4A, 4B and 4C show a cannula part which can be used in connection with the invention.

Figure 5 shows a front view of an inserter which can be used in connection with the invention.

Figure 6 shows a view from the proximal side of the inserter of fig. 5.

Figure 7 shows a connector part which can be part of an infusion part according to the invention.

Figure 8 shows the same connector part as fig. 7 without the bubble membrane covering the inlet.

Figure 9A and 9B show a cannula part having an inclined contact surface.

Figure 10A-10D show an enlargement of the contact between the cannula part and the cannula opening of the connection part.

Figure 11A, B and C show an embodiment of a base part provided with a fluid path mainly constructed of a tube.

Figure 12 shows an embodiment of an infusion part having an angle d = 90° between insertion direction and tangent to contact surface.

Figure 13 shows a cannula part which can be used in connection with the invention.

Fig. 1 shows an embodiment of an infusion part comprising a cannula part and a fluid path according to the invention. This embodiment comprises a surface plate 1 attached to a contact surface. The surface plate 1 is in this embodiment constructed of a molded plastic material and the contact surface can be the proximal side of a mounting pad 2 which mounting pad 2 is unreleasably fastened to the surface plate 1 during manufacturing of the device. The mounting pad 2 of this embodiment has the same area as the surface plate 1 but it could be of an area larger or smaller than the surface plate 1.

A connector part 3 is position on the surface plate 1. The connector part 3 provides for the contact between the base part and some kind of delivery

means. According to one embodiment the surface plate 1 and at least an outer cover of the connector part 3 is simply molded in one piece during manufacturing of the device. The internal parts of the connector part 3 forms a fluid path between e.g. a reservoir of medication or a reservoir for liquid collected from the patient and a cannula part 7. Therefore the connector part 3 is provided with at least two openings, one opening at each end of the fluid path where the first opening 13 is an inlet or outlet opening receiving or delivering fluid to a not shown reservoir and the second opening is an inlet or outlet opening 12 receiving or delivering fluid to a cannula part 7. The connection part 3 might be provided with extra openings e.g. for inserting the cannula part, for injection of a second medication or nutrient or for letting the fluid in the fluid path get in contact with a sensor.

In the following the first opening 13 will be referred to as "inlet" and the second opening will be referred to as "outlet" although the direction of the flow through the fluid path is not significant for the invention.

The embodiment of fig. 1 is provided with two guiding means 4 in the form of two right angled L-shaped profiles in the form: ┐ ┌, which profiles are protruding from the surface plate 1 of a base part having a lower or proximal side which is fastened to the skin of the patient. The guiding means 4 correspond to guiding means on a delivery part or a cover or connecting means which are to be fastened to the base part during use. Such corresponding means can e.g. be formed as one or more hooks having an L-shaped profile in the form: └ and ┘ corresponding to the profiles on the base part.

The fluid path of the connection part 3 of this embodiment is very short and the inlet 13 of the connection part 3 is placed in a centre position in relation to the guiding means 4. The top of an inserted cannula part 7 is shown inserted into the connection part 3.

The connection part 3 is further provided with a cannula cavity 12A which accurately fits around a cannula part 7 i.e. the cannula cavity 12A has the same 3-dimensional shape or profile as the cannula part 7 and is just big

enough to let the cannula part 7 pass through and then fit into the opening. In fig. 1 the cannula part 7 is shown in a position where the cannula part 7 is fully inserted. When the cannula part 7 is fully inserted, then the upper surface i.e. the distal surface of the cannula part 7 is normally at level with or at a lower level than the outer surface of the connection part 3 around the cannula cavity 12A.

When the cannula part 7 has been fully inserted into the connection part 3, an opening 20 in a side surface of a body 24 of the cannula part 7 corresponds to the opening 12 of the fluid path of the connection part 3 and fluid can flow from one part to the other. The opening 12 might in the following be referred to as an "outlet" although the direction of the flow is not significant to the invention.

Figs. 2 and 3 show a second embodiment of an infusion part according to the invention. A delivery part corresponding to this embodiment could be joined to the base part by pushing the delivery part down toward the guiding means 4 which in this case is a longitudinal raised platform having a magnet 5 fastened to the top surface. The delivery part would be provided with a corresponding magnet e.g. of a smaller or different size than the magnet 5 which is placed in such a way e.g. in a track corresponding to the raised platform 4, that the corresponding magnet of the delivery part can slide along the magnet 5 on the raised platform 4 of the base part in the longitudinal direction. When the delivery part arrives at its working position, two release handles can engage respectively with two protruding parts 15 protruding from the upper surface of the surface plate 1. When the delivery part is in its working position it is locked in any horizontal direction by the release handles and in the direction perpendicular to the surface plate 1 by the two corresponding magnets of respectively the delivery part and the base part. These locking mechanisms make it possible to fasten and release the delivery device from the base part as often as needed i.e. a single-use base part can be combined with a multi-use delivery part.

In fig. 2 and 2A the base part is shown without the cannula part 7 and in fig. 3 the base part is shown having the cannula part 7 in a positioned reached just

before insertion of the cannula part 7, normally the cannula part 7 would at this stage of insertion still be placed inside an inserter and it would not be visible.

Normally an inserter 10 holds the cannula part 7 before insertion and the insertion can be initiated by pushing a handle 11. Fig. 5 and 6 shows the direction the handle 11 has to be pushed in, in order to initiate insertion of the cannula part 7. After insertion a not shown insertion needle can be retracted to the inside of the inserter 10 and the inserter 10 is removed from the base part, leaving an inserted cannula 22 fastened to the surface plate 1. If the cannula 22 of the cannula part 7 is a hard self penetrating cannula there will be no separate insertion needle and therefore no need to retract the insertion needle.

In figs. 2 and 2a the connection part 3 is shown with an outer cover provided by the molded surface plate 1. The outer cover shown in this embodiment is not an independent unit but is attached unreleasably to or simply made as a part of the surface plate 1 e.g. by a molding process. The outer cover is provided with a cannula cavity 12A for the cannula part 7 and an access opening 13 for e.g. a reservoir thereby allowing access to the fluid path of the connection part 3 by the reservoir and the cannula part 7. The cannula cavity 12A allows the cannula part 7 to be inserted sub- or transcutaneous into the patient within the circumference of the hard surface plate 1 and the contact surface 2 of the base part which in this embodiment is provided by a mounting pad is also provided with an opening 12B which allows for the cannula to be inserted (see fig. 7 and 8). This opening 12B is not necessary if the contact surface 2 is constructed of such a material and thickness that it can be penetrated by at least the cannula 22 of the cannula part 7.

In figs. 7 and 8 the connection part 3 is shown without the outer cover provided by the molded surface plate 1. In order to secure a fluid tight connection between the outlet opening 12 in the connection part 3 and the cannula part 7 the outlet opening 12 of the connection part 3 is provided with an elastic sealing 18 around the outlet opening 12. When the cannula part 7 is inserted it will be press fitted into the cannula opening 12 and the elastic

sealing 18 will provide a completely fluid tight gasket around the corresponding openings 12 and 20. In order to improved the press-fitting and thereby the fluid tight connection between the cannula part 7 and the outlet of the fluid path, the cannula cavity 12A can be provided with a decreasing cross-section in a plane parallel to the cannula 22 when inserted and perpendicular to the surface where the outlet of the fluid path is positioned. The cannula part 7 will have a corresponding decreasing cross-section.

In order to secure a fluid tight connection between the inlet opening 13 in the connection part 3 and the reservoir 6, a bubble shaped membrane 17 has been positioned around the first opening 13. The membrane 17 completely covers the inlet opening 13 and prevents contamination of the internal of the connection part 3. When a reservoir or connecting parts for a reservoir is pressed towards the connection part 3, a connector needle 19 will penetrate the membrane 17 and provide a completely fluid tight transfer of fluid between the connection part 3 and the reservoir.

That the membrane 17 is bubble shaped means that it is attached around the opening – normally around the edge of the opening – it protects and the membrane 17 protrudes from the planed formed by the edge of the opening and forms a dome in a distance from the edge which distance normally corresponds to the length of a connector needle 19.

In fig. 8 the connector needle 19 is shown as being a part of the connection part 3 i.e. it is attached to the connection part 3 but it might just as well be a part of the reservoir.

According to one embodiment the connection part 3 is provided with both a connector needle 19 and a bubble shaped self closing membrane 17 and the reservoir is also provided with a bubble shaped self closing membrane. As both parts are provided with self closing membranes it will be possible to separate the two units from each other and rejoin them at a later time without the internal fluid path of the connection part 3 and thereby the patient being contaminated.

Fig. 4A, 4B and 4C shows an enlargement of a cannula part 7 which can be used in connection with the invention. This embodiment comprises a body 24 provided with a cannula 22 and with a protruding front 25 having a flat surface. The surface of the cannula part 7 having an opening need not be flat; it can actually have any desired shape as long as it is possible to create a corresponding surface on the connection part 3 facing the cannula part 7. In one embodiment the front 25 is inclined in such a way that the cross-section at the upper i.e. distal end is larger than the cross-section at the proximal end, i.e. the enc closest to the patient after insertion, of the front in at least one dimension. The front 25 is provided with an opening 20 through which liquid can exit or enter the cannula part 7. The body 24 is further provided with a top opening 21 which opening can be covered with a self closing membrane. The opening 21 need some kind of entrance protection as it is facing an outer surface which is in contact with the surroundings. The top opening 21 is primarily used when inserting the cannula part 7 if the cannula 22 is a soft cannula. That the cannula 22 is soft means that is made of a relatively soft material which can not penetrate the patients skin, in this case it is necessary to use a pointy insertion needle of a relatively hard material when inserting the cannula and this pointy needle can be inserted through the top opening 21, pass through an inner through going opening in the body 24 of the cannula part and further pass through the full length of the cannula 22 in such a way that the pointy end of the insertion needle stick out of the open end of the hollow cannula 22. After insertion i.e. after the cannula 22 has been placed sub- or transcutaneous in the patient, then the insertion needle is retracted and the cannula 22 is left inside the patient.

The cannula part 7 is also provided with fastening means 23 which fastening means 23 lock the cannula part 7 to the base part at the time where it is fully inserted. The fastening means 23 of this embodiment comprises outward hooks that can pivot around an axe close to the body 24 of the cannula part 7 in such a way that the diameter formed by the outermost edge of the hooks can be reduced when the hooks are pressed inward i.e. towards the centre of the cannula part 7. When the pressure is removed the hooks will return to their original position due to the flexibility of the material. The hooks will be pushed inwards when they pass an opening such as e.g. the opening 12B or a

corresponding opening in the surface plate having a cross-section which at least in one dimension is smaller than the outer edge of the hooks and as the hooks return to their original position after having passed through the opening, the hooks will lock the cannula part 7 in the inserted position.

Figs. 5 and 6 show an inserter that can be used to position the cannula part 7 in the base part. The inserter comprises a housing 10 provided with an internal opening where the cannula part 7 can be moved from a retracted position to a forward position. In the retracted position the cannula 22 is not in contact with the patient and in the forward position the cannula 22 is inserted into the patient. The inserter further comprises an actuator handle 11 which is to be activated when the cannula part 7 is to be inserted and it comprises fastening means 14 which means can lock the inserter to the base part before and during insertion. Normally the inserter should be fastened to the base part under sterile conditions or the joined base part and inserter should be sterilized after fastening of the inserter in order to prevent contamination of the cannula cavity 12A, and in order to reduce the amount of material placed on the patient's skin it is desirable to be able to remove the whole of or at least part of the inserter after the cannula part 7 has been inserted.

Figs. 9A and 9B show an enlargement of a second embodiment of a cannula part 7. Fig. 9A shows the cannula part 7 in a state just before insertion and fig. 9B shows the cannula part 7 inserted into the cavity 12A in the base part.

This embodiment also comprises a body 24 provided with a cannula 22 and with a protruding part 25 having a flat surface provided with an opening 20. According to this embodiment the protruding part 25 is inclined in such a way that the pressure between the opening 20 and the sealing 18 around the second opening 12 of the connection part 3 is increased, also the sealing 18 is subjected to less tear during insertion. The inclination of the inclined part 25 is defined by the angle d between the centre line c of the cannula 22 (the centre line c is parallel to the insertion direction) and a line parallel to the surface around the opening 20. If the surface around the opening 20 is not

straight, then the line parallel to the surface would be the tangent to the surface around the opening 20. The angle d will be larger than 0° and smaller than or equal to 90°, normally d ∈]0°, 30°] depending on the diameter or the protrusion of the sealing 18 or [60°, 90°[. The distance d_1 measured at the distal end of the surface of the protruding inclined part 25 where the distal end is the end of the cannula part 7 which is furthest away from the patient after insertion, between the surface of the protruding inclined part 25 and the centre c of the cannula part 7 is larger than the distance d_2 between the surface of the protruding part 25 at the proximal end i.e. the end closest to the patient after insertion, and the centre c of the cannula part 7. Normally the distance d_2 will be so small that the proximal end of the protruding inclined part 25 does not touch the sealing 18 of the connection part 3 during insertion.

In one embodiment (not shown) the angle d is close to 90° i.e. d = 90°, such an embodiment would in a drawing corresponding to fig. 9A and 9B appear to have an upward opening 12 of the connection part 3 fitting to a downward opening 20 of the cannula part 7. This means that the force pushing the cannula part 7 toward the sealing 18 will be close to perpendicular to the contact surface of the sealing 18 and this will prevent that the sealing is distorted during insertion of the cannula part 7 by the cannula part 7 sliding along the sealing 18.

In another embodiment (shown in fig. 4A-C and in fig. 10A-B) d = 0° as the protruding part 25 and the centre line c are parallel. According to this embodiment the cannula part 7 will be in sliding contact with the protruding sealing 18 which can cause the sealing to be distorted.

The protruding front 25 of the cannula part 7 need not be flat; it can actually have any desired shape e.g. partly spherical as long as it is possible to create a corresponding surface on the connection part 3 facing the cannula part 7. Also the opening 20 of the protruding front 25 can behave as an inlet or an outlet depending on the purpose of the cannula part 7. In fig. 9A and 9B which is a cut-through view it is shown how the top opening 21 of the body 24 is covered with a self closing membrane 21A. As according to the embodiment

of fig. 4A-C the top opening 21 is primarily used when inserting the cannula part 7 if the cannula 22 is a soft cannula but the top opening 21 can also be used to inject medication or nutrients other than the primary medication which could be e.g. insulin which the patient receive via the opening 20.

This embodiment of the cannula part 7 is also provided with fastening means 23 and in this embodiment the fastening means 23 has the form of a protruding part 23 on the cannula part 7 which corresponds to a flexible part 23A on the stationary base part. The flexible part 23A can be pushed outward as indicated with an arrow at fig. 9A when the protruding part 23 on the cannula part 7 passes during insertion of the cannula part 7. After insertion the upward surface of the protruding part 23 of the cannula part 7 will be locked by the downward surface of the flexible part 23A of the base part and it will not be possible to detach the cannula part 7 from the base part.

The cannula part 7 of fig. 9A and 9B is provided with a soft cannula 22 which soft cannula 22 together with a bushing 29 provides a cannula assembly. This assembly is normally fastened inside the body 24 of the cannula part 7 by an interference fit i.e. it is only the friction between the body 24 and the cannula assembly which keeps it in the correct position. In order to prevent the cannula assembly from sliding back through the upper larger opening in the body 24 of the cannula part 7, the body 24 of the cannula part 7 can be provided with a ring shaped recess encircling the exit for the soft cannula 22. As the recess creates an open space around the soft cannula 22, the soft cannula 22 can form a small bulk i.e. a ring shaped bulk which prevents the soft cannula from sliding back.

Fig. 10 illustrates how the unrestricted openings between the cannula part 7 having the body 24 and the fluid path having the inlet/outlet opening12 slide into place. Fig. 10A and 10B show an embodiment where d = 0°and fig. 10C and 10D show and embodiment where d is around 15°, normally between 8-22°. According to the embodiment of fig. 10A and 10B the body 24 of the cannula part 7 is provided with an inclined edge in order to reduce distortion or tearing of the sealing. In both embodiments the shown sealing 18 is a circular or cylindrical silicone unit which is placed in a round track around the

inlet/outlet opening 12 in the connection part 3. The wall where the sealing or gasket 18 has been placed is provided with an adjacent expansion room 28. After positioning of the cannula part 7 the sealing 18 can occupy this room. In the embodiment of fig. 10C and 10D is not only the sealing face angled, the whole cylindrical sealing part 18 is angled in order to allow uniform sealing deformation. The cylindrical sealing 18 does not form the walls of the inlet/outlet opening 12, the wall or surfaces of this opening is formed by the material which the connection part 3 is formed of in order to provide a pipe which cannot be deformed. In order to create the necessary pressure between the seal and the seal face i.e. the surface which the sealing 18 touches when in a sealing position, the sealing face can be provided with a small continuous protrusion protruding from the sealing face and having the same shape as the sealing which would e.g. be circular if the sealing has the cylindrical shape shown in fig. 10A-D.

Figs. 11A-11C show one embodiment of a connection part 3. Fig. 11A show the embodiment of the connection part 3 in an exploded view where the internal holding parts 61 for a tube 60 providing a fluid path is shown. Fig. 11B shows a cut through the internal holding part 61 according to which it is possible to the position of the tube 60. Fig. 11C shows an enlargement of the encircled part of fig. 11A.

According to the present embodiment the connection part 3 and the surface plate 1 is molded in one piece of a plastic material, the connection part is provided with several openings, one opening is the cavity 12A which is prepared for fitting in the cannula part 7 and another opening is prepared for fitting in the internal parts of the connection part 3. The internal parts of the connection part 3 according to this embodiment comprises one tube which at two positions are bend in 90° i.e. both the inlet and the outlet end of the tube 60 points in the same direction perpendicular to the connecting part of the tube 60 where the connecting part of the tube 60 forms the fluid path between the two bending parts.

At one end the tube 60 is protected by a bubble shaped membrane 17 and at the other end the tube 60 is open and unprotected, but the open tube end is

surrounded by a sealing 18 which is attached unreleasably to a holding part 61. When the internal parts have been placed in the corresponding opening in the connection part 3 a cover 62 accurately fitting in the opening is placed in level with the surface of the connection part 3 in such a way that the user experience a smooth surface which cannot be tampered with.

The embodiment of the base part shown in fig. 11A is provided with guiding means 26 placed inside the cavity 12A of the connection part 3. The two opposing ribs 26 which constitute the guiding means correspond to closely fitting openings 27 in the cannula part 7. The guiding means 26 and the corresponding parts 27 on the cannula part can have other forms, the important feature is that they correspond to each other and make it possible for the cannula part 7 to slide into use position.

Fig. 11B shows an enlargement of the internal parts of the connection part 3. The holding parts 61 comprise a single molded part which is providing a stable embedment of the tube 60. The open end of the tube 60 opens into a space surrounded by the sealing 18. The closed end of the tube 60 is completely surrounded by a soft membrane. "Completely surrounded" means that the there is no free access to the surroundings, "soft membrane" means that the membrane can be penetrated by a needle, especially the connector needle 19 which is provided by the end of the tube 60 and which is embedded inside the soft membrane. The end of the tube 60 which constitutes the connector needle 19 is in this embodiment not actually in touch with the surrounding membrane 17. The connector needle 19 is surrounded by air, and the internal space surrounding the connector needle 19 has a cylindrical or conical shape i.e. a circular cross-section. The walls of the membrane 17 will deform by bending inwards or outwards when the length of the membrane is reduced as a result of the applied pressure.

Fig. 11C shows an enlargement of the enclosed field marked in fig. 11A.

Fig. 12 shows an embodiment of an infusion part where the angle d = 90°. The inlet/outlet opening 12 is constructed as a pointy end of a tube 60 which provide for the fluid path or connection between the reservoir 6 and the

cannula part 7. A membrane e.g. self closing protects the entrance to the reservoir 6 which means that micro organisms cannot access the reservoir 6 when the reservoir is removed from the connection part 3.

Fig. 13 shows yet an embodiment of a cannula part 7 which can be used with an infusion part according to claim 1. The body 24 of the cannula part 7 has the shape or profile of a truncated cone i.e. in each horizontal (according to fig. 13) cross-section of the body it is round having varying diameters. The body 24 is provided with two permanently attached circular sealings or gaskets 18. Between these two gaskets 18 is the opening 20 positioned which opening 20 allows for fluid to enter the inner through going opening of the cannula part 7. The cannula part 7 is to be placed in a below illustrated connection part 3 provided with a corresponding cavity 12A also having the shape of a truncated cone. The cavity 12A has an inlet/outlet opening 12 for fluid flowing to or from the cannula 22.

Claims

1. An infusion part comprising a cannula part (7) and a fluid path,
- the cannula part (7) comprises a body (24) formed by a hard material which body (24) has an inner through going opening which through going opening is in fluid contact with a cannula (22), the cannula (22) has an inner opening which provides fluid contact with the patient, the body (24) of the cannula part (7) has an opening (20) corresponding to the inlet or outlet opening (12) of the fluid path resulting in fluid contact between the fluid path and the cannula part (7) and these two corresponding openings (12, 20) do, when they are positioned opposite each other, allow unrestricted flow
- the fluid path comprises at least one inlet and one outlet opening (12, 13) through which a fluid can enter and exit the fluid path, and
- a sealing (18) is positioned between the cannula part (7) and the inlet/outlet opening (12) of the fluid path when the cannula part (7) is in position for use in order to keep the fluid path to the cannula tight,
characterized in that the sealing (18) is surrounding the inlet/outlet opening (12) *and/or* the distance d_1 between a centre line c of the cannula part and a point on the outer surface of the cannula part positioned at or above the upper edge of the sealing (18) is larger than the distance d_2 between the centre line c of the cannula part and a point on the outer surface of the cannula part positioned at or below the lower edge of the sealing (18).

2. An infusion part according to claim 1, **characterized in** that the body (24) of the cannula part (7) is provided with a sealing (18) before use.

3. An infusion part according to claim 1 or 2, **characterized in** that the opening (12) of the fluid path is provided with a sealing (18) before use.

4. An infusion part according to claim 2 or 3, **characterized in** that the sealing material (18) is hydrophobic and elastic.

5. An infusion part according to claim 4, **characterized in** that the sealing material (18) is made of silicone.

6. An infusion part according to any of the claims 1-5, **characterized in** that the body (24) of the cannula part (7) has at least a second opening (21) to the inner through going opening.

7. An infusion part according to claim 6, **characterized in** that the second opening (21) to the inner through going opening is covered by a self closing membrane which membrane can be penetrated by a blunt or pointy needle.

8. An infusion part according to any of the claims 1-7, **characterized in** that the infusion part comprises a base part (1, 2, 3) which can be fastened to a patient's skin.

9. An infusion part according to claim 8, **characterized in** that the base part (1, 2, 3) is provided with a cavity (12A) corresponding to the 3-dimensional profile of the non-penetrating end of the cannula part (7).

10. An assembly according claim 9, **characterized in** that the cavity (12A) extends below the outer surface of the base part (1, 2, 3) providing walls which tightly fits around the cannula part (7) when the cannula part (7) is inserted into the patient.

11. An assembly according to claim 10, **characterized in** that the inlet/outlet opening of the fluid path (12) opens into the wall of the cavity (12A) fitting around the cannula part (7) and when the cannula part (7) is inserted, the opening (20) of the cannula part (7) corresponds to the opening of the fluid path (12).

12. An assembly according to any preceding claim, **characterized in** that the angle between the direction of insertion of the cannula part (7) and a plane

being tangent to the surface surrounding the opening opposite the sealing (18), is named d and $0 < d \leq 90^{\circ}$.

13. An infusion part according to any of the claims 8-12, **characterized in** that the base part (1, 2, 3) is formed at least partly of a hard material (1, 3).

14. An infusion part according to any of the claims 8-13, **characterized in** that the fluid path is formed as an integrated part of the base part.

15. An infusion part according to claim 13 or 14, **characterized in** that the hard material is a molded plastic material.

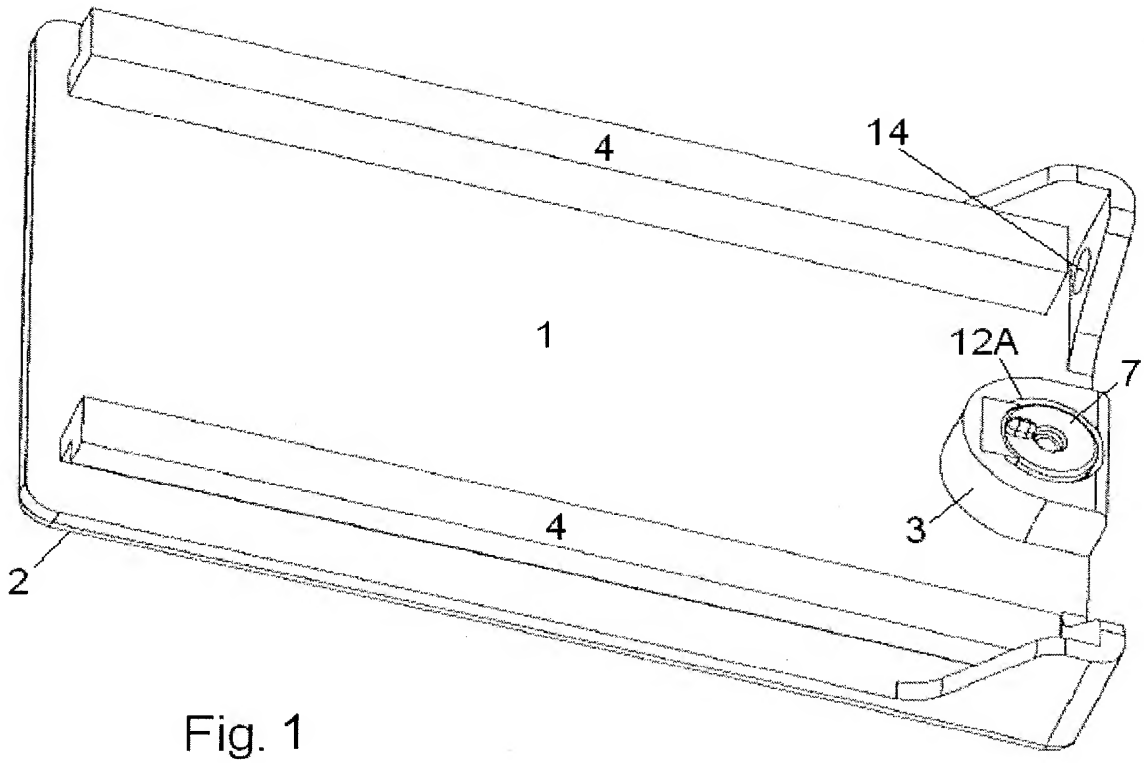

Fig. 1

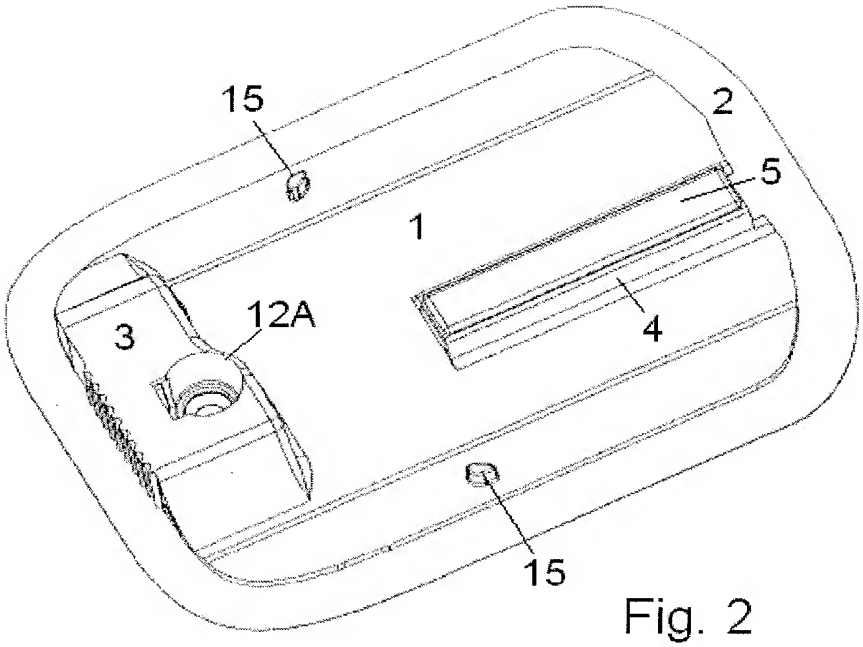

Fig. 2

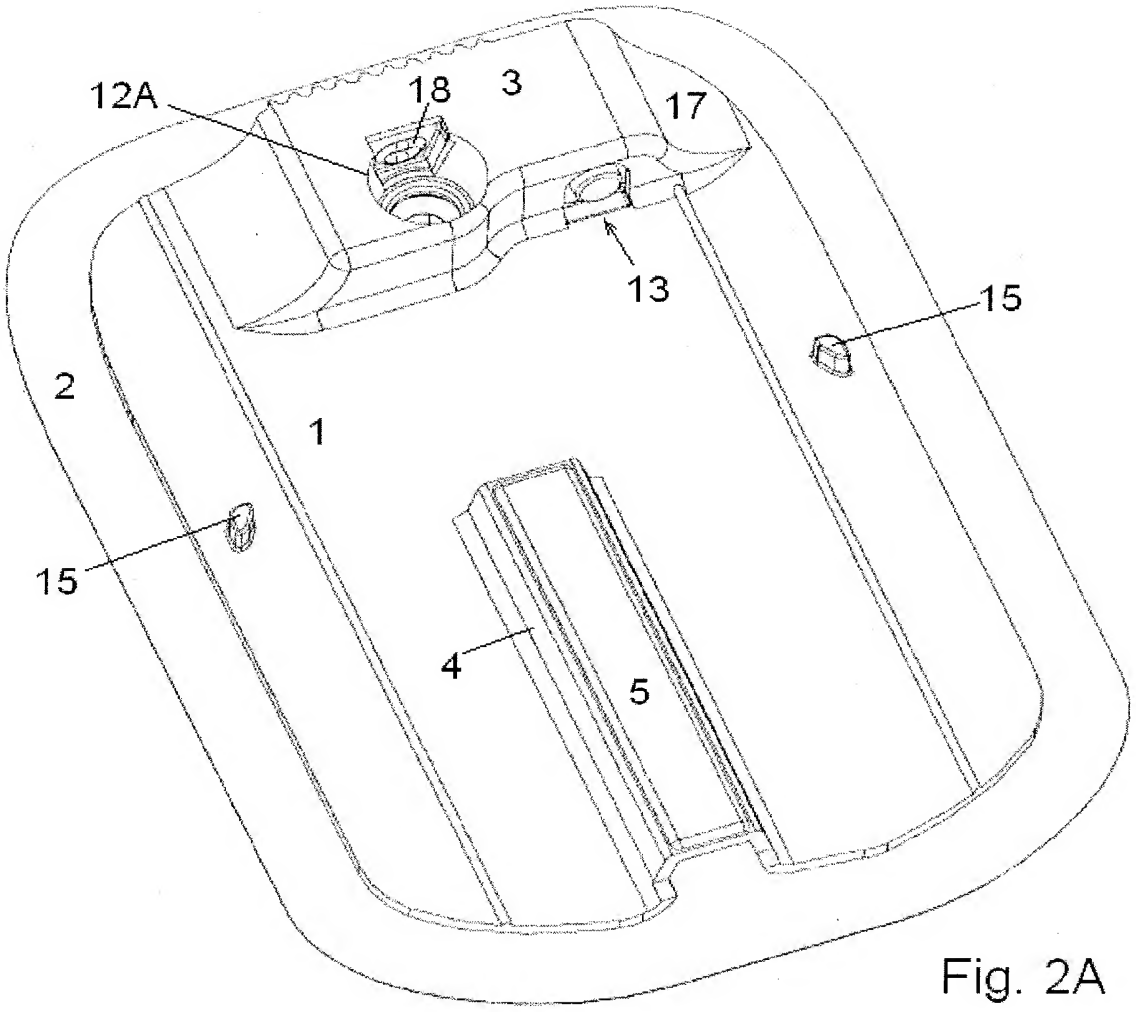

Fig. 2A

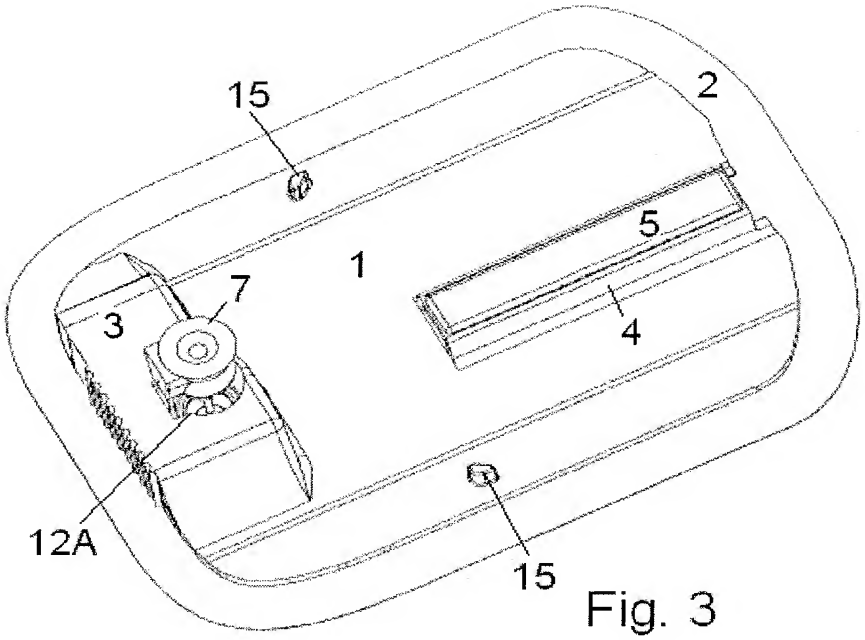

Fig. 3

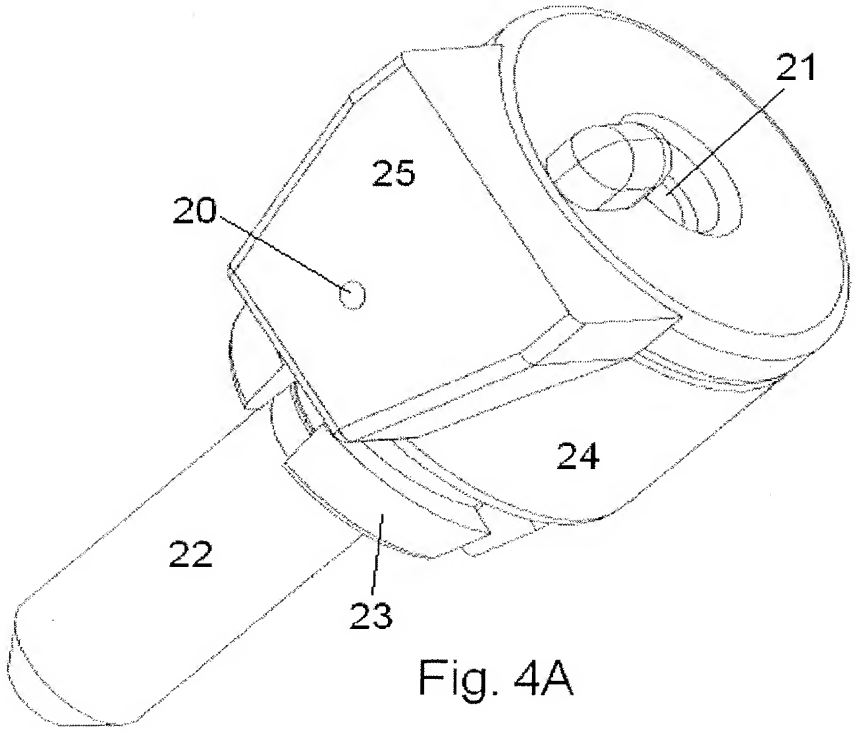

Fig. 4A

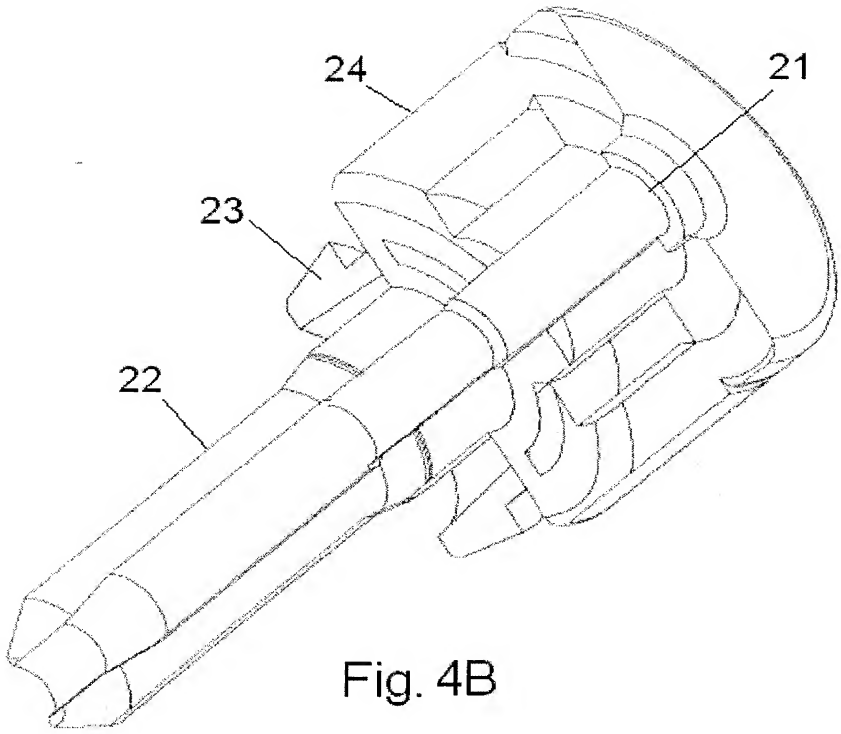

Fig. 4B

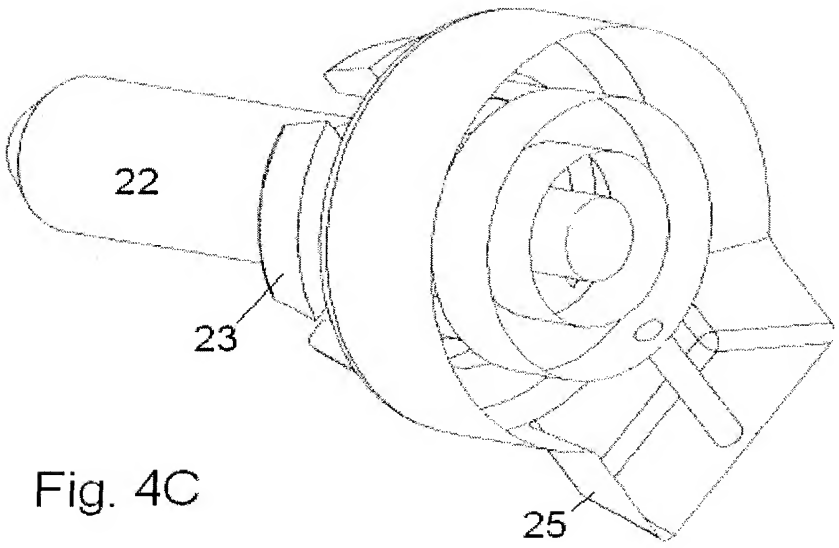

Fig. 4C

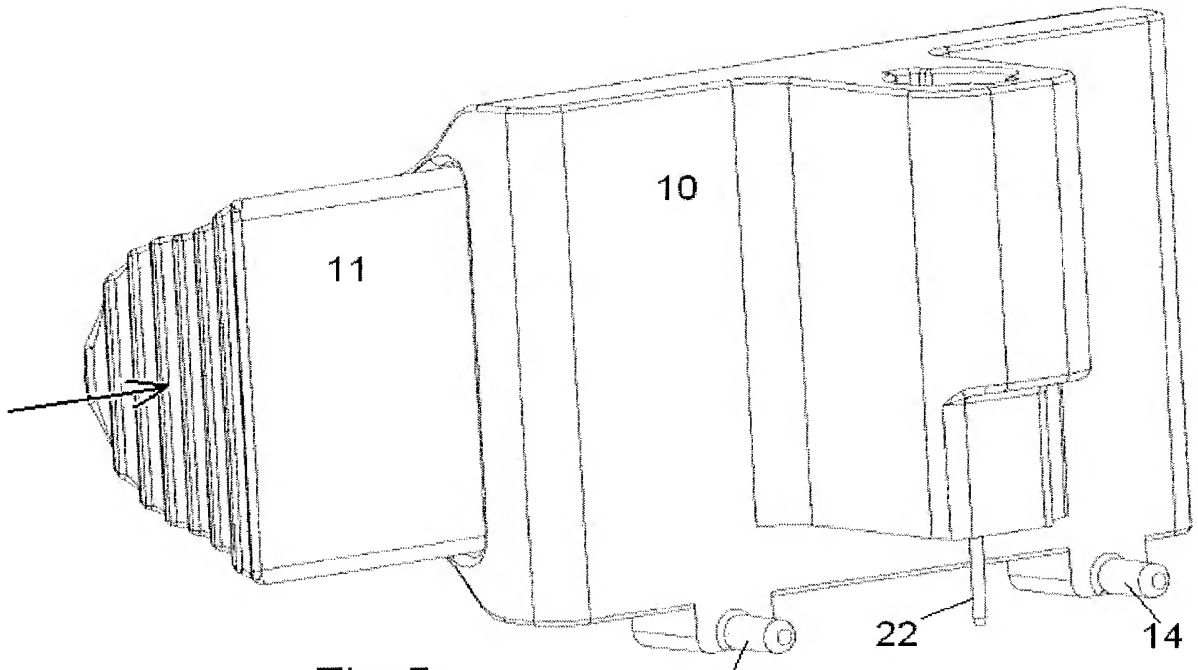

Fig. 5

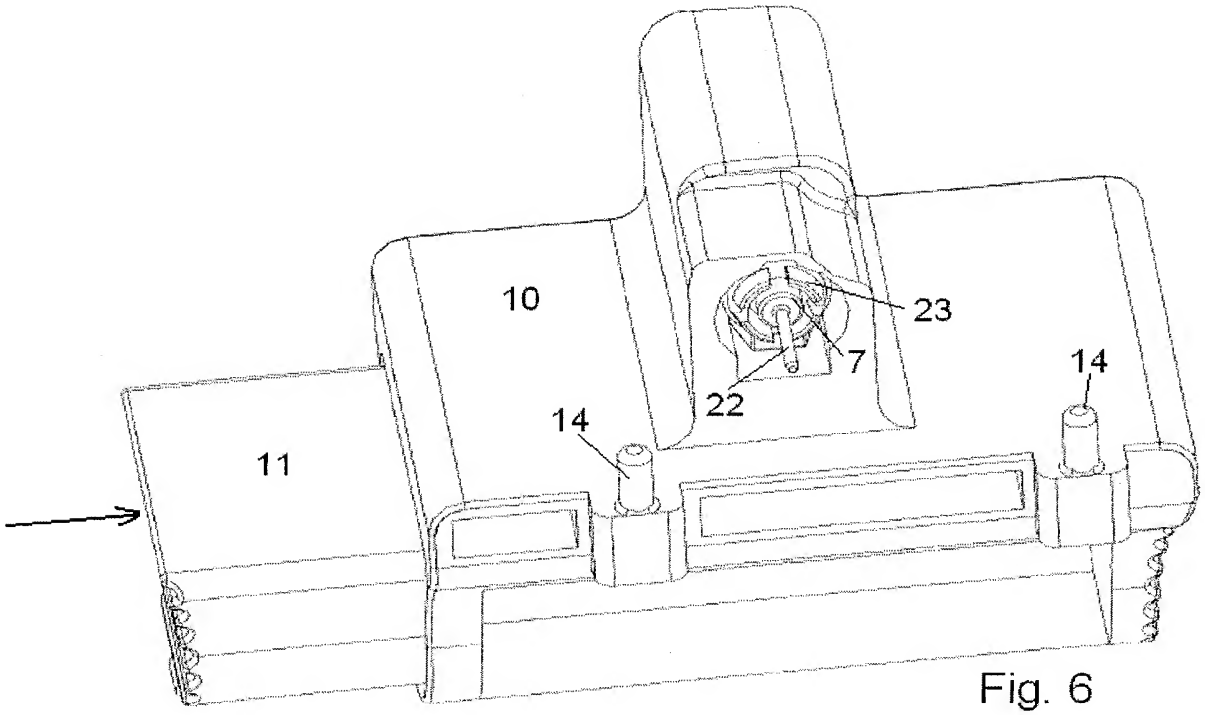

Fig. 6

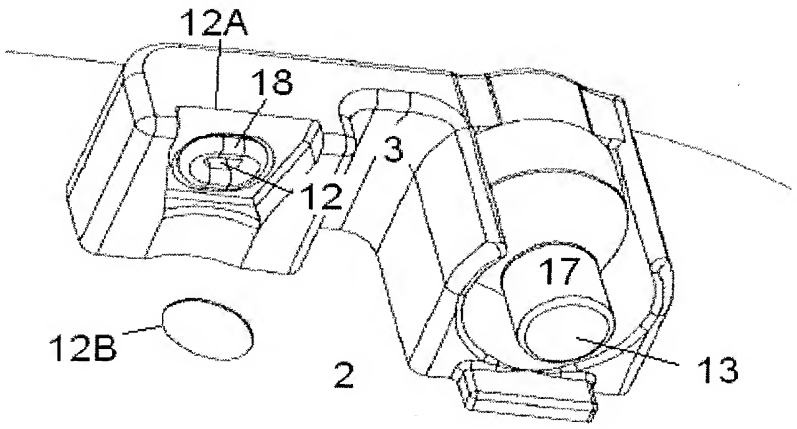

Fig. 7

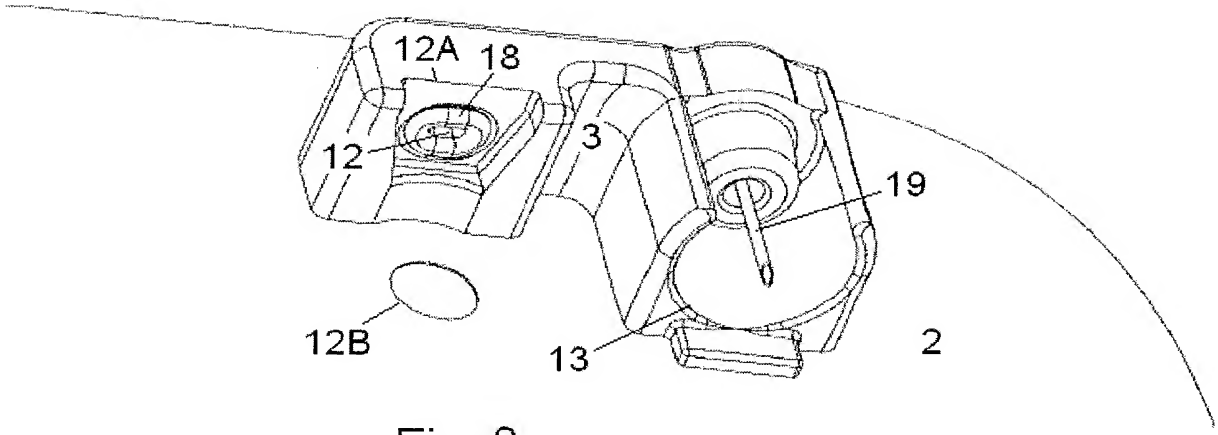

Fig. 8

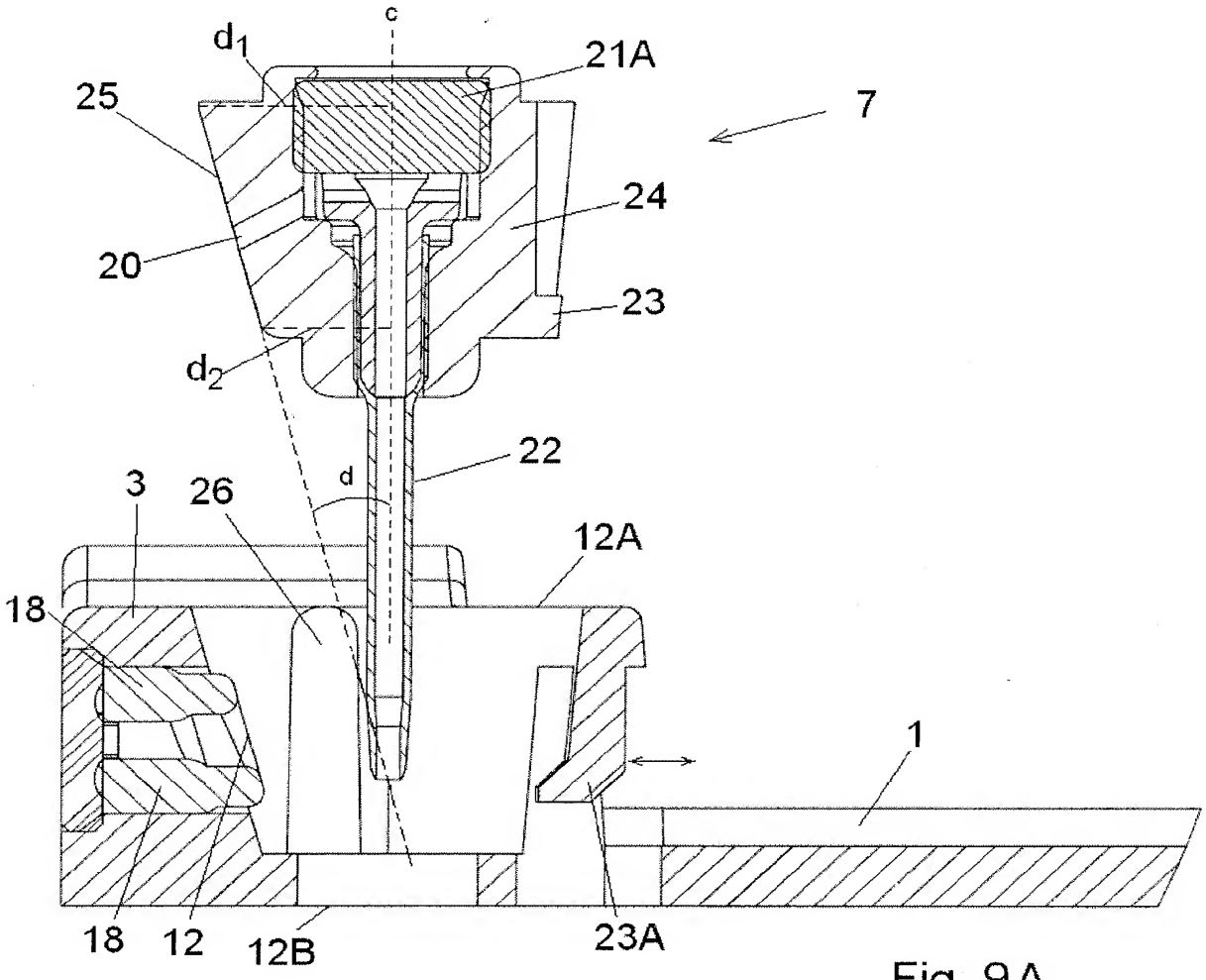

Fig. 9A

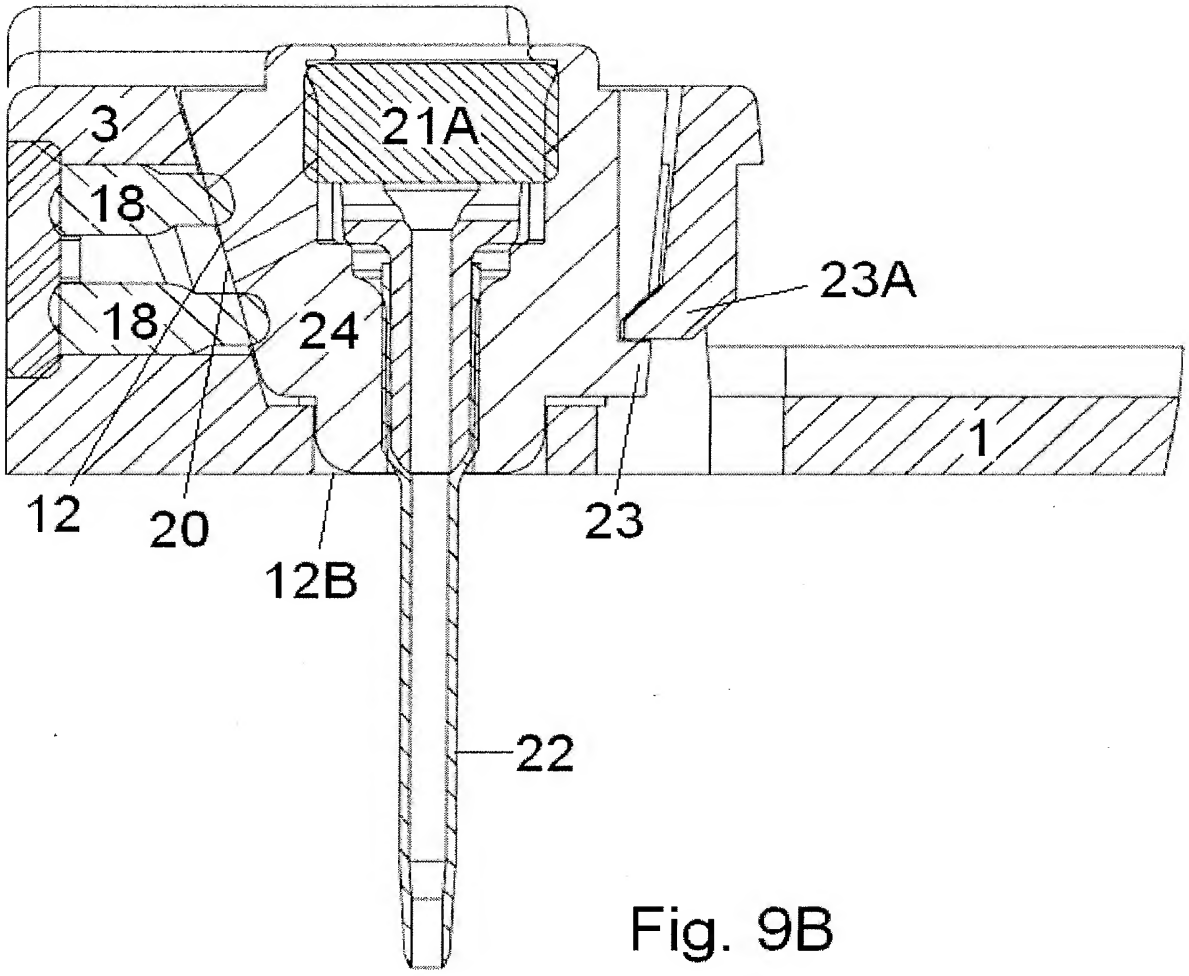

Fig. 9B

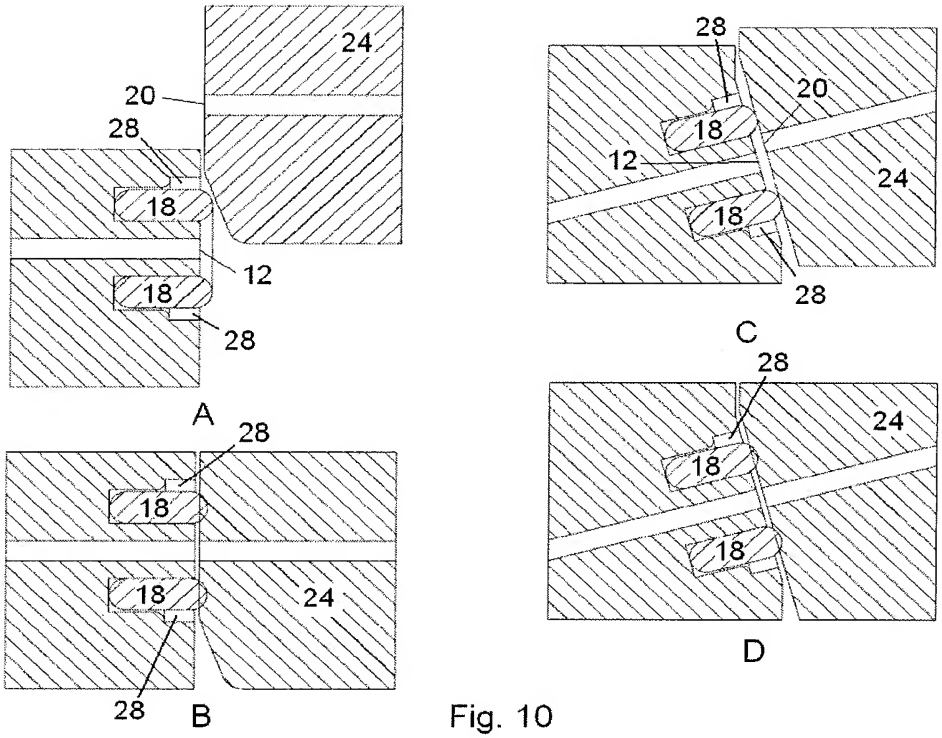

Fig. 10

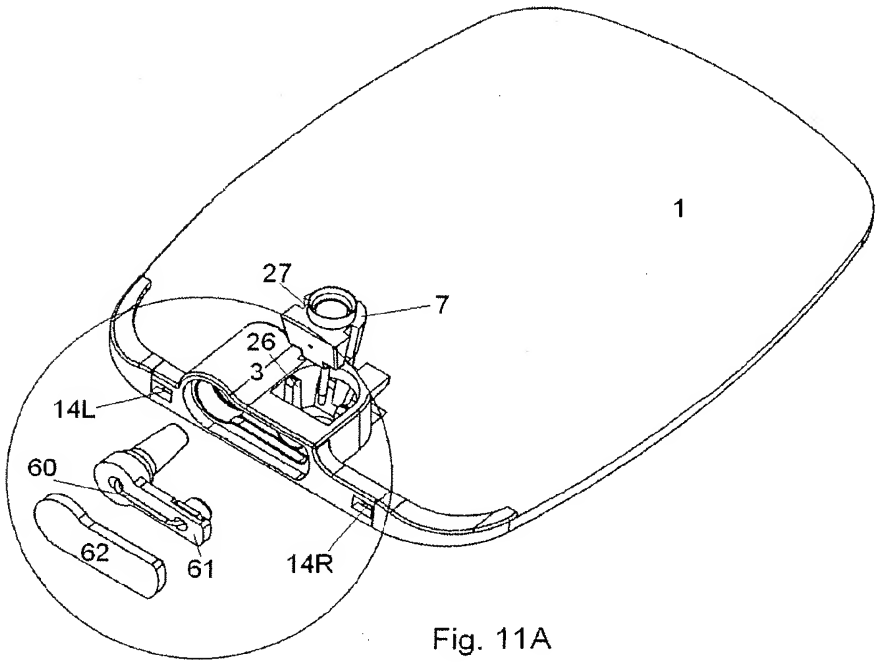

Fig. 11A

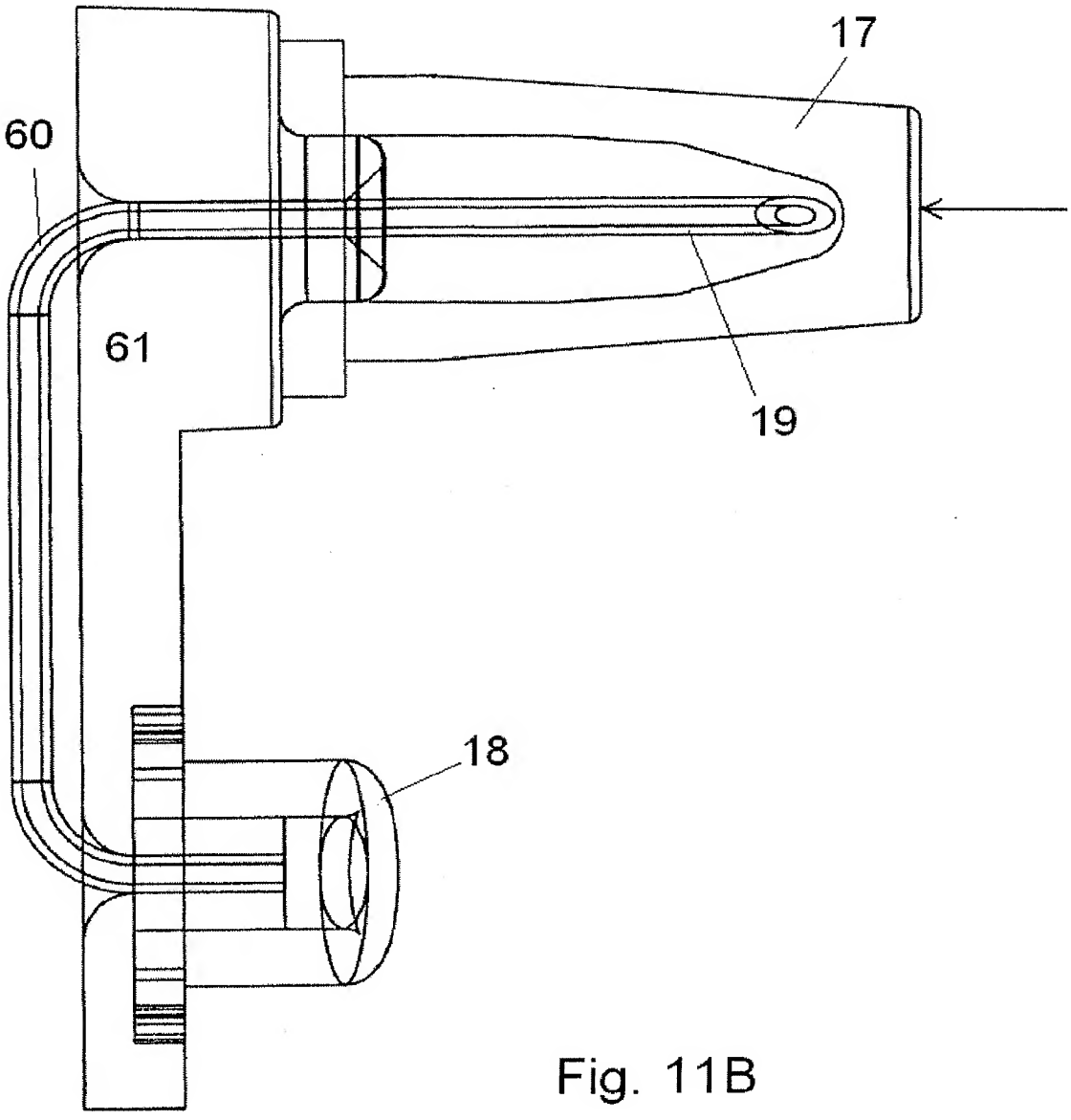

Fig. 11B

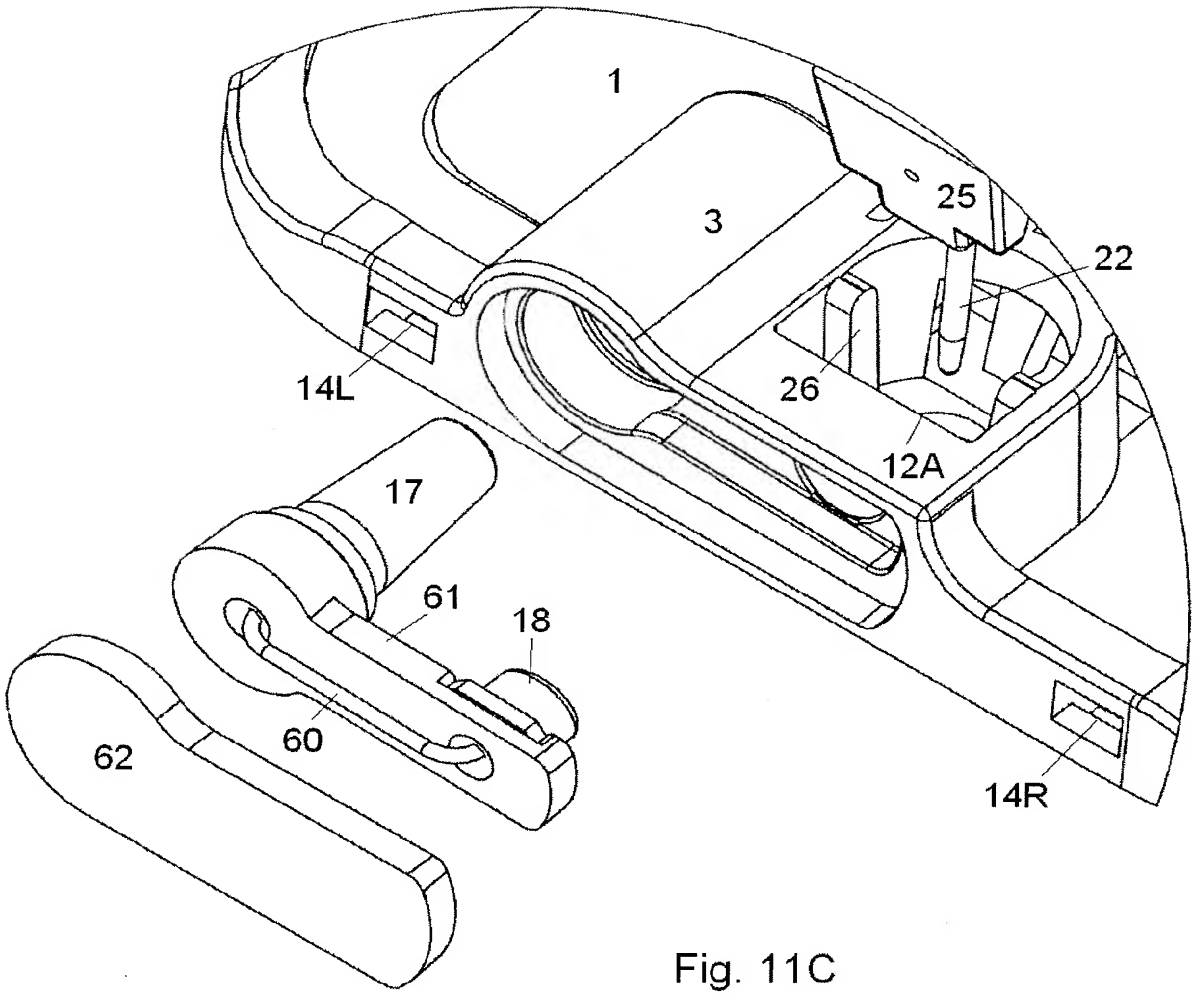

Fig. 11C

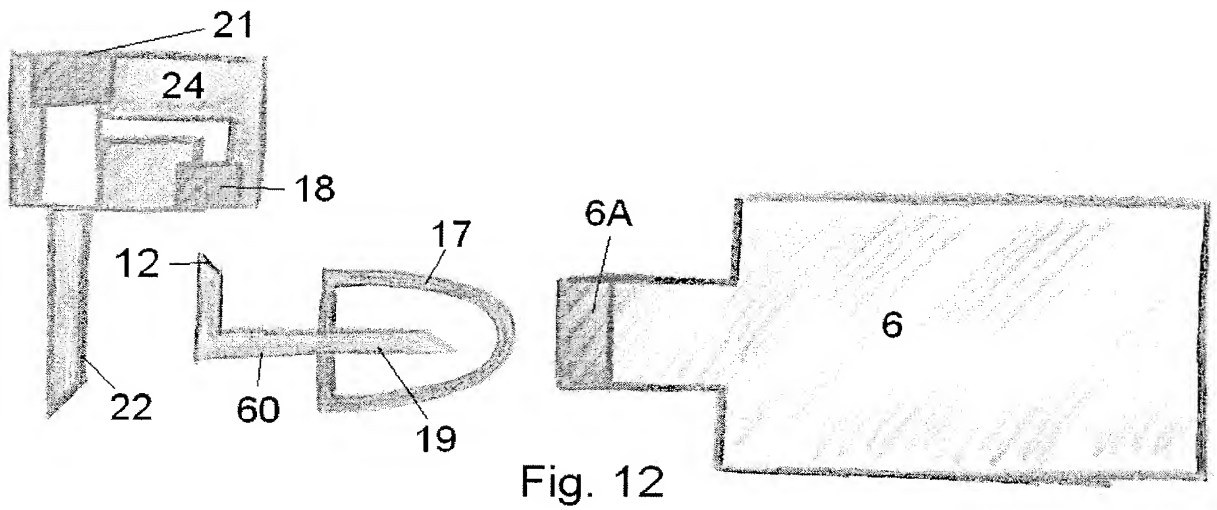

Fig. 12

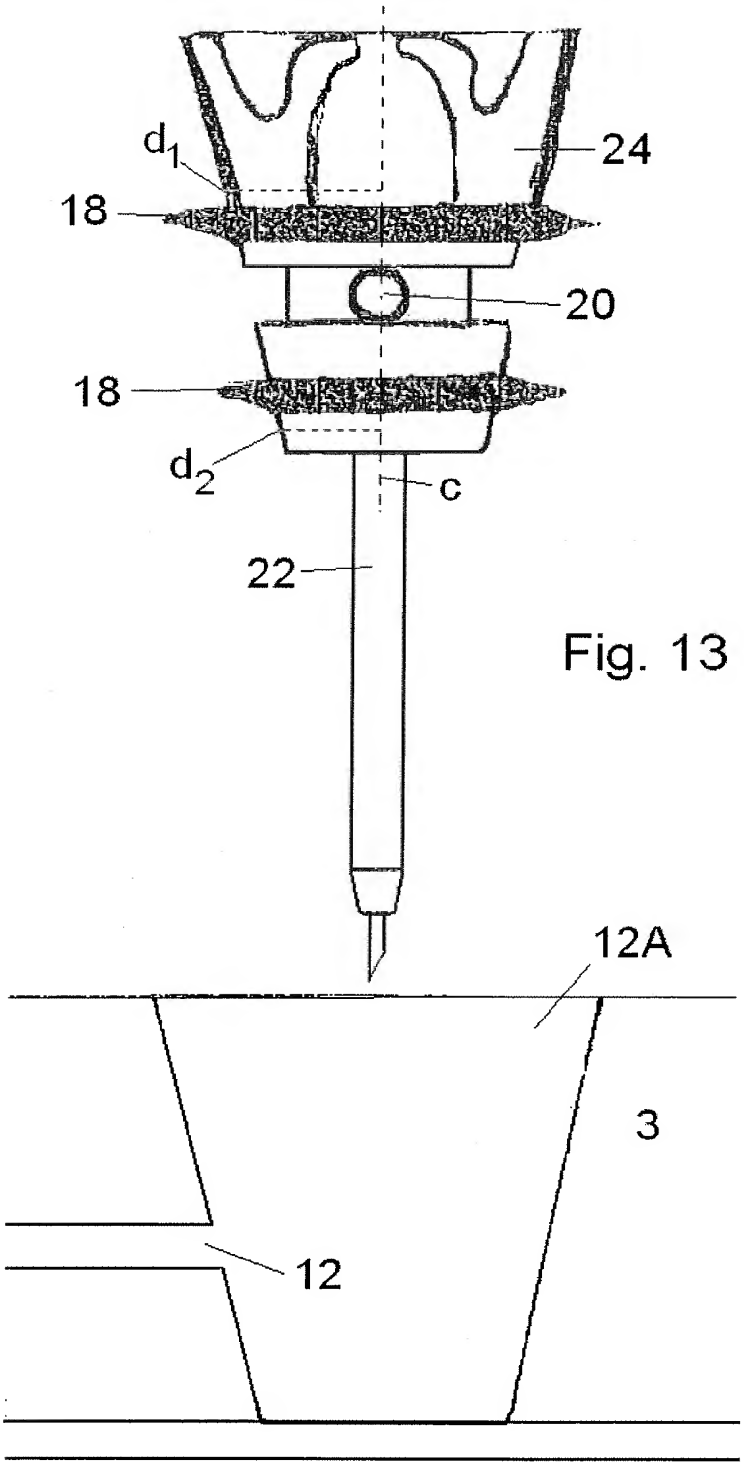

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/051634

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/158

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 652 027 A (HOFFMANN LA ROCHE [CH]) 10 May 1995 (1995-05-10) column 2, lines 39-47 figures	1-15
A	EP 0 272 530 A (HOFFMANN LA ROCHE [CH]) 29 June 1988 (1988-06-29) figures	1-15
A	US 6 620 140 B1 (METZGER ANJA [US]) 16 September 2003 (2003-09-16) figures 1,2	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 May 2009	27/05/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schultz, Ottmar

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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